



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP15

Copayments for Medications in 2015

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with changes, an interim final rule amending the Department of Veterans Affairs (VA) medical regulations to freeze the copayments required for certain medications provided by VA until December 31, 2015. Under that interim final rule, copayment amounts were maintained at the same rates as they were in 2014 (which were \$8 for veterans in priority groups 2-6 and \$9 for veterans in priority groups 7 and 8), and would have increased based on the prescription drug component of the Medical Consumer Price Index (CPI-P) on January 1, 2016. This final rule extends the current freeze for copayments through December 31, 2016.

DATES: Effective date: This rule is effective on [insert date of publication in the Federal Register].

Applicability date: The provisions of this final rule shall apply to the copayments discussed herein as of January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Kristin Cunningham, Director, Business Policy, Chief Business Office (10NB), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 382-2508. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: An interim final rule amending VA's medical regulations concerning the copayment required for certain medications was published in the Federal Register on October 27, 2014. 79 FR 63819.

VA invited interested persons to submit comments on the interim final rule on or before December 26, 2014, and we received four comments. All four commenters supported the interim final rule, which maintained copayment rates for medications at their current levels throughout 2015. One commenter disagreed with part of the rationale for the rule. VA explained in the interim final rule that part of the rationale for the rule is to reduce the incentive for veterans to seek care from other health care providers and plans, as fragmentation of care can increase the risk of adverse interactions and harm to the patient because it is more difficult for each provider to assess if the patient is taking any other medications.

The commenter further recommended that VA should ensure the ability of non-VA providers to easily communicate with VA to treat patients, monitor prescriptions, and reduce wait times. Normally when VA authorizes care from a non-VA health care provider, we require the provider to submit medical record information to VA so that we have a complete account of what care and treatment was provided to a veteran. Many veterans receive care and services from other providers that are not authorized by VA,

and in these situations, our health care providers may not have a complete account of the veteran's care. To the extent that non-VA providers can and do share information with VA, the risk of an adverse event declines, and VA fully supports such efforts. However, since the effect of the rulemaking is to temporarily freeze certain copayments and not establish monitoring or communication standards, VA does not make any changes to this rulemaking.

The commenter also urged VA to allow veterans to fill prescriptions written by civilian family physicians at VA pharmacies to reduce significant financial challenges for veterans and to maintain consistency with the delivery of pharmaceutical benefits to veterans. However, this recommendation is outside the scope of this rulemaking, which deals only with establishing copayment rates for medications prescribed by and filled by VA. Therefore, VA is not making any changes based on this comment.

One commenter suggested extending the freeze for at least an additional two to three years, to alleviate what the commenter deemed an "undue hardship" on veterans caused by increased pharmacy copayments. To the extent that increased pharmacy copayments have been shown to reduce utilization of VA pharmacy benefits (as stated in the interim final rule), we agree with the commenter that extending the freeze for at least one additional year is in the best interest of veterans. We would therefore extend the freeze in this final rule to be effective through December 31, 2016. This extended timeframe would permit the freeze to be in effect all of calendar year 2016 for the continued benefit of veterans, and would allow VA to continue to develop and publish proposed and final rules to implement a tiered copayment structure for medication copayments, which will further align VA's medication copayment structure with other

Federal agencies and the commercial sector. Therefore, VA is extending the copay freeze in this final rule to be effective through December 31, 2016.

VA is adding an applicability date paragraph to the preamble to clarify that the amendments made by this rulemaking applied to the copayments discussed herein as of January 1, 2015. This is a clarifying, non-substantive change.

Based on the rationale set out here and in the interim final rule, VA is adopting the provisions of the interim final rule as a final rule with the change to extend the freeze as described above.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601- 612. This final rule will temporarily freeze the copayments that certain veterans are required to pay for prescription drugs furnished by VA. This final rule directly affects only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the final regulatory flexibility analysis requirements of 5 U.S.C. 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined that it is a significant regulatory action under Executive Order 12866 because it is likely to result in a regulatory action that may have an annual effect on the economy of \$100 million or more. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www.va.gov/orpm/>, by following the link for VA Regulations Published from FY 2004 through fiscal year to date.

Congressional Review Act

VA has determined that this regulatory action is considered a major rule under the Congressional Review Act, 5 U.S.C. 801-08, because it may result in an annual effect on the economy of \$100 million or more. In the preamble to the interim final rule (79 FR 63819, 63821), we stated that although this regulatory action may constitute a major rule within the meaning of the Congressional Review Act, 5 U.S.C. 804(2), it was not subject to the 60-day delay in effective date applicable to major rules under 5 U.S.C. 801(a)(3) because the Secretary found that good cause existed under 5 U.S.C. 808(2) and made this regulatory action effective on January 1, 2015, consistent with the

reasons given for the publication of this regulatory action as an interim final rule.

Increasing the copayment amount on January 1, 2015, might have caused a significant financial hardship for some veterans and may have decreased patient adherence to medical plans, and could have had other unpredictable negative health effects. VA anticipates the same risk for financial hardship and decreased patient adherence if copayments were increased in calendar year 2016, and has therefore extended the freeze through December 31, 2016. Accordingly, the Secretary found that additional advance notice and public procedure thereon were impractical, unnecessary, and contrary to the public interest. In accordance with 5 U.S.C. 801(a)(1), VA submitted to the Comptroller General and to Congress a copy of this regulatory action and VA's Regulatory Impact Analysis.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.005, Grants to States for Construction of

State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on May 5, 2015, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: September 10, 2015

Michael P. Shores,
Chief Impact Analyst,
Office of Regulation Policy & Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The authority citation for part 17 continues to read as follows:

AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

§17.110 [AMENDED]

2. Amend § 17.110 in paragraphs (b)(1)(i) through (iii) and (b)(2), by removing all references to “December 31, 2015” and adding in their place “December 31, 2016”.

[FR Doc. 2015-23162 Filed: 9/15/2015 08:45 am; Publication Date: 9/16/2015]